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BASIC RESEARCH STUDY

Accurate nonfluoroscopic guidance and tip location of peripherally inserted central catheters using a conductance guidewire system

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Background: **Bedside placement of peripherally inserted central catheters (PICCs) may result in navigation to undesirable locations, such as the contralateral innominate or jugular vein, instead of the superior vena cava or right atrium. Although some guidance and tip location tools exist, they have inherent limitations because of reliance on physiological measures (eg, chest landmarks, electrocardiogram, etc), instead of anatomical assessment (ie, geometric changes in the vasculature). In this study, an accurate, anatomically based, non-X-ray guidance tool placed on a novel 0.035" conductance guidewire (CGW) is validated for PICC navigation and tip location.**

Methods: **The CGW system uses electrical conductance recordings to assess changes in vessel cross-sectional area to guide navigation of the PICC tip. Conductance rises and oscillates when going in the correct direction to the superior vena cava/right atrium, but drops when going in the incorrect direction away from the heart. Bench and in vivo studies in six swine were used to confirm the accuracy and repeatability of the PICC placement at various anatomical locations. The PICC tip location was confirmed by direct visualization vs the desired location.**

Results: **CGW PICC guidance was highly accurate and repeatable with virtually no difference between actual and desired catheter tip location. The difference between the CGW PICC location vs the desired target was -0.07 ± 0.07 cm (6.6% error) on the bench and 0.04 ± 0.10 cm (5% error) in vivo. No complications or adverse events occurred during CGW usage.**

Conclusions: **The CGW provides an anatomically based, reproducible, and clinically significant method for PICC navigation and tip location that can improve accuracy, decrease the wait time prior to therapy delivery, decrease cost, and minimize the need for X-ray. These findings warrant clinical evaluation of this navigation tool for PICC line placement. (J Vasc Surg: Venous and Lym Dis 2013;1:202-8.)**

Clinical Relevance: **This paper describes impedance technology (a conductance guidewire [CGW]) utilized as a new platform for accurate peripherally inserted central catheter (PICC) line delivery. The CGW has the ability to function as a standard platform for over-the-wire delivery and acts as a novel system for device navigation without the need for fluoroscopy or X-ray. Ultimately, the CGW described here is clinically relevant, as it provides an accurate, anatomically relevant, and reproducible method for PICC delivery that can improve accuracy, decrease the wait time prior to therapy delivery, decrease cost, and minimize X-ray exposure for both patients and clinicians.**

Peripherally inserted central catheters (PICCs) are long-term central venous implants used in many applications including drug administration, blood sampling, total parenteral nutrition, and hemodialysis.[1,2] PICC placement can occur in various settings, ranging from the radiological suite to the bedside, and it requires patient informed consent and placement by a specialized clinician (radiologist or specialized nurse with catheter training).[1-3] Accurate PICC placement is important since improper tip positioning may result in catheter dysfunction, cardiac tamponade, or cardiac arrhythmias.[1,2,4-6] As a result, these complications increase clinical time and cost, and, if left unattended, can result in serious consequences or even death. To minimize these complications and maximize therapy delivery, PICC tips should be placed in the lower one-third of the superior vena cava (SVC) or in the right atrium (RA).[1,2,7-10]

The majority of PICCs are placed by nurses at the patient bedside and require subsequent X-ray confirmation of the catheter tip location by a radiologist prior to catheter usage.[3] At bedside, PICC tips are misplaced up to 30% of

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the time to various locations, such as the contralateral innominate or jugular vein, and thus require readjustment and possible follow-up X-ray confirmation.[3,11-13] As a result of tip misplacement, efforts have been made to develop PICC guidance technologies to aid in bedside PICC delivery. All current guidance technologies, however, have inherent limitations because they attempt to find vascular anatomical positions based on physiological measurements or body surface landmarks.[14-20] Therefore, there is a need for an anatomically based (ie, vascular anatomy), non-X-ray method for accurate bedside PICC delivery that will require little training and be reliable for various patient populations. In this study, we describe the use of a novel conductance guidewire (CGW) system that provides real-time feedback to the clinician for accurate PICC line navigation and tip location.

METHODS

The CGW system provides navigation and tip location feedback to the clinician through a console screen display that shows increased conductance and oscillations during CGW advancement in the correct direction towards the SVC/RA junction, but sustained decreased conductance during CGW advancement in the incorrect direction away from the SVC/RA (eg, jugular). The complete CGW system consists of three components: the CGW, the connector handle, and the console (Fig 1). The CGW is a 0.035" 180-cm guidewire consisting of a floppy/atraumatic distal tip, a tetrapolar measurement electrode section, a long coiled body around a solid core, and a stiff proximal end for easy manipulation and attachment to the connector handle. Previous testing has shown equivalence in mechanical performance (eg, torqueability and pushability) between the 0.035" CGW and the Wholey Hi-Torque Guidewire System. The excellent mechanical properties of the CGW allow for easy steerability, withdrawal, and re-advancement when conductance feedback demonstrates that navigation is occurring in the wrong direction away from the SVC/RA junction. The connector handle allows for connection of the CGW for measurements and disconnection of the CGW for over-the-wire device delivery with no loss of functionality. The console continually displays the conductance results and provides feedback about the PICC position. The console provides this feedback by injecting a small, safe amount of alternating electric current (AC) through the distal outer electrodes of the CGW and acquiring, filtering, and displaying the measured conductance across the distal middle electrodes.[21-24] A further description of the Ohm's Law basis for the conductance CGW measurements can be found in the Appendix (online only).

During advancement of the CGW from the initial access vein (typically the cephalic, brachial, basilica, or saphenous vein) to the axillary vein, the subclavian vein, the brachiocephalic vein, the SVC, and the RA, the measured conductance will show step increases as the guidewire reaches a new, larger vessel, while navigation away from the SVC/RA will result in decreases in conductance. The point at which there is the largest absolute conductance coupled with large pulsatile conductance changes denotes the location of the cavoatrial junction (Fig 2). When the CGW has located the region of interest for catheter placement, the CGW is held in place, and the PICC is advanced over the wire until the measured conductance drops very abruptly to nearly zero. When this occurs, the tip of the PICC line will have arrived at the desired location because the catheter will have covered up the middle electrodes (the device measurement site) and caused the CGW to sense the cross-sectional area (CSA) of the catheter (ie,

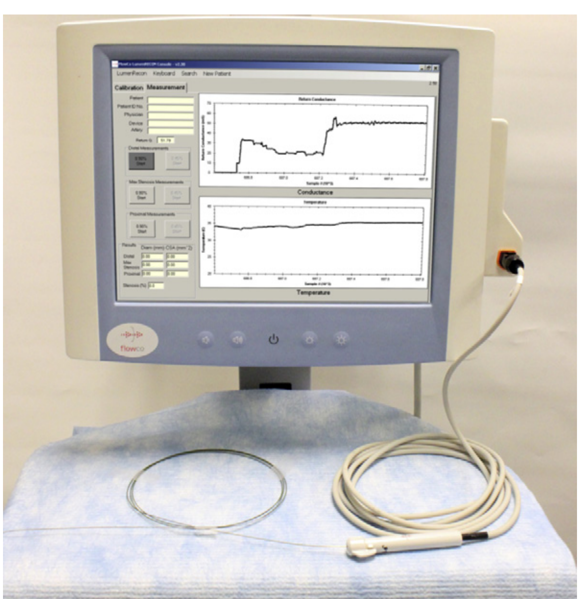


Fig 1. The conductance guidewire (CGW) system consisting of console, connector handle, and guidewire.

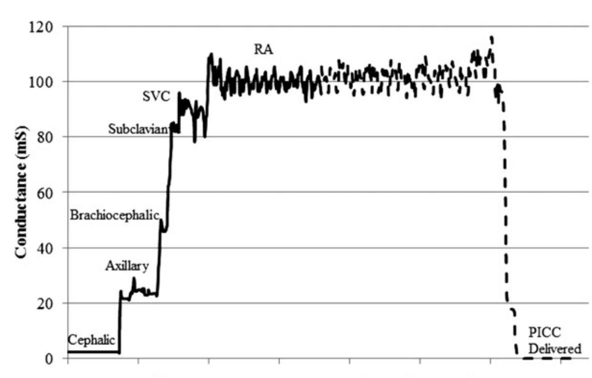


Fig 2. In vivo conductance guidewire (CGW) navigation and tip location profile. The *solid* and *dashed lines* represent forward advancement of the guidewire (*GW*) and no guidewire movement/advancement of the peripherally inserted central catheter (*PICC*) line, respectively. *RA,* Right atrium; *SVC,* superior vena cava.

almost zero conductance) compared with what it sensed previously in the SVC space (ie, larger CSA/conductance).

Thus, the CGW has the ability to function as a standard platform for over-the-wire delivery and acts as a novel system for device navigation and tip location. Below is a description of the bench and in vivo validation of the CGW system for PICC delivery.

Bench validation. A series of rigid phantoms consisting of four consecutive segments with diameters of 6.4 mm, 9.5 mm, 13 mm, and 15 mm were connected and filled with 0.9% NaCl solution (Baxter Healthcare Corporation, Deerfield, Ill). Side branches (starting diameter = 6.4 mm) were also attached to the 9.5-mm tubing.

Validation of the CGW system to properly deliver the PICC to various locations within the simulated anatomy (ie, 1.3 cm, 1.6 cm, and 2 cm proximal to the junction between the 13-mm and 15-mm tubing) was performed by a single user (MS) using three CGWs in randomized order, using only feedback from the console. To assess system accuracy and repeatability, the difference between the PICC tip vs the desired location in the phantom (accuracy) and the difference between the PICC tip for each repeat run (repeatability) was calculated. To assess the system deviation, identity line and Bland-Altman plots, along with mean, standard deviation, and root mean square error (RMS) calculations were made for the accuracy and repeatability.[25] To establish the relationship between total conductance (G_T) and CSA/L, conductance was measured with the CGW in a series of 4-mm to 16-mm rigid phantoms filled with 0.9% NaCl solution.

Animal validation. Six swine (body weight = 53 ± 10 kg) were used for in vivo validation of CGW PICC navigation and tip location. Sedation was accomplished via an intramural injection of TKX (4.4 mg/kg of a mixture of telazol [50 mg/mL], ketamine [25 mg/mL], and xylazine [25 mg/mL]). An anesthetic plane was established via intubation and ventilation with 100% oxygen and 1% to 2% isoflurane. The cephalic vein was located, punctured, and cannulated with a ~4F sheath. The CGW was then placed in the sheath, the CGW was connected to the connector handle, the connector handle was connected to the console, and the CGW and PICC were advanced into the vasculature together (PICC locked in place during advancement). The target location for the PICC tip was the lower SVC ~2 cm away from the cavoatrial junction.

In one animal, a series of radiographic images were taken of the venous pathway with contrast. The CGW conductance was recorded at each location along the path in 1-cm increments, the diameter of the vessel was measured angiographically, and the venous blood conductivity was measured with a Rho cuvette (Millar Instruments, Inc, Houston, Tex). Equation 1 (Appendix, online only) was used to calculate the parallel conductance (G_p) at each location along the venous pathway. The relationship between the percentage of the G_T attributed to G_p as a function of CSA was then obtained.

After PICC placement, the animal was terminated via an anesthetic overdose, and the chest and heart were opened to measure the position of the PICC tip relative to the cavoatrial junction. The animal studies were approved by the Institutional Animal Care Use Committee at Indiana University-Purdue University Indianapolis and in accordance with the Animal Welfare Act, Institute of Laboratory Animal Research guidelines, and the Public Health Service policy.

RESULTS

PICC navigation was achieved in vivo (Fig 2) and in vitro (Fig 3) through visualization of a series of step increases during CGW advancement without the use of X-ray. Once the cavoatrial junction was identified by the CGW, as seen by the absolute largest conductance and oscillations (ie, RA pulsatility effect), PICC tip location was achieved by over-the-CGW advancement until the conductance dropped to near zero (Fig 2).

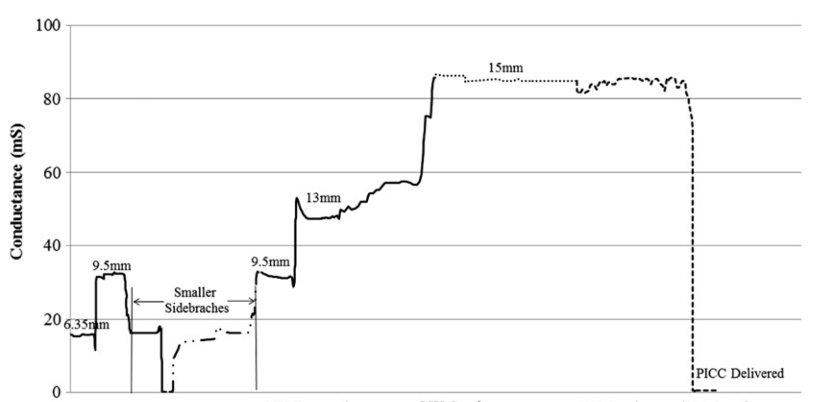


Fig 3. Bench conductance guidewire (CGW) navigation and tip location profile. The *solid, solid and dotted, dotted,* and *dashed lines* represent forward advancement of the guidewire (*GW*), retraction of the guidewire, no guidewire movement, and no guidewire movement/advancement of the peripherally inserted central catheter (*PICC*) line, respectively.

Bench validation (Fig 3) provided a similar profile to in vivo (Fig 2) during advancement. During usage on the bench, the CGW provided feedback when the guidewire advanced in the correct direction towards the simulated cavoatrial junction (ie, large conductance step increases) and when the guidewire was advanced in the incorrect direction (ie, conductance continually dropped when advancing into the smaller side tubes). When incorrect advancement occurred, the CGW was retracted (Fig 3, *dashed dotted lines*) to the previous location in which the conductance was the highest. The guidewire was then re-advanced in the correct direction as evidenced by the step increases in conductance at each new location in the simulated anatomy. Once the simulated cavoatrial junction was identified, the CGW was held stationary, and the PICC was advanced over the wire until the conductance reading dropped almost to zero (Fig 3, *dashed lines*). The near-zero conductance drop was attributed to the CGW sensing the small CSA of the PICC, instead of the large CSA of the 15-mm tubing.

PICC placement on the bench was highly accurate and repeatable. The RMS error for accuracy and repeatability for all CGWs and distances was 6.6% and 3.8%, respectively. Accuracy (Fig 4, *a* and *b*) and repeatability (Fig 5, *a* and *b*) was -0.07 ± 0.07 cm and -0.01 ± 0.06 cm for the desired distances from 1.3 cm to 2.0 cm.

A highly linear relationship was found for the conductance as a function of CSA on the bench (Fig 6, *a*; $R^2 = 1.00$) and for the percentage of G_T attributed to G_p (%G_p) as a function of vessel CSA in vivo (Fig 6, *b*; $R^2 = 0.96$).

PICC placement in vivo was highly accurate and confirmed in each animal after the procedure through direct visualization of the catheter in the vasculature upon termination (Fig 7, *a* and *b*). The RMS accuracy was 5.1% for the PICC tip location relative to the desired target of 2 cm proximal to the cavoatrial junction for all animals (Table; Fig 7, *a* and *b*).

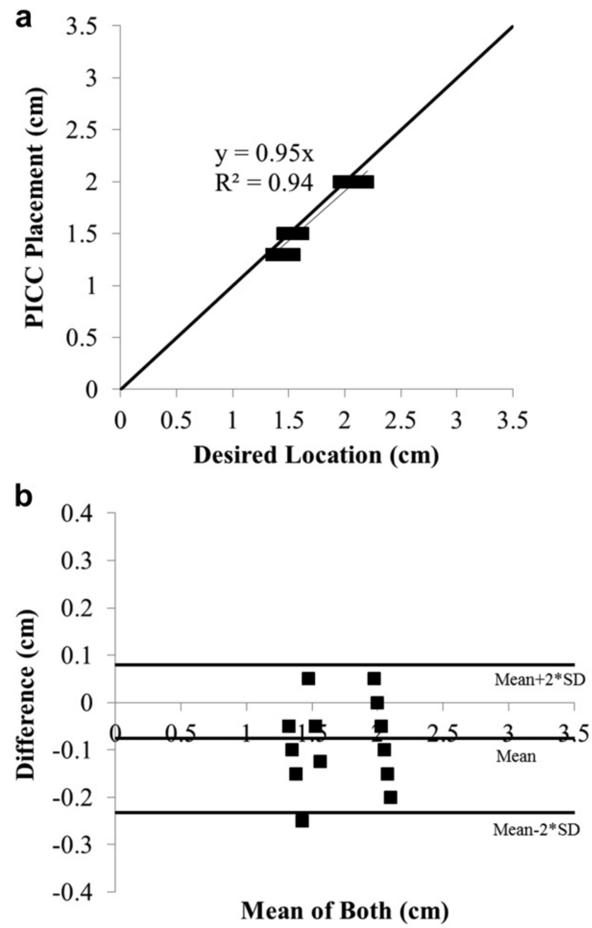


Fig 4. Accuracy data for bench experiments showing **(a)** the measured distance for the peripherally inserted central catheter (*PICC*) placement vs the desired, target location, which was proximal to the simulated cavoatrial junction at 1.3 cm, 1.6 cm, and 2 cm distances. The *solid dark line* is the identity line and the *smaller dark line* is the regression. Also shown is the **(b)** accuracy Bland-Altman analysis. *SD,* Standard deviation.

DISCUSSION

The CGW system provides an accurate, anatomically based method for PICC delivery. Results from the bench and animals demonstrated important anatomical landmarks (ie, the cavoatrial junction) can be accurately and repeatedly located solely with the CGW system (no need for fluoroscopy or X-ray for confirmation). The accuracy of the CGW system is based on Ohm's Law that directly relates measured electrical conductance to vessel CSA (equations 1 and 2 in the Appendix, online only). Our previous studies in arteries[24] and work here in the venous system (Fig 6, *b*) confirm that G_p is inversely related to vessel CSA. This inverse relationship between G_p and vessel CSA minimizes the role of G_p in larger organs and further magnifies the identification of important landmarks during advancement into larger venous vessels, like the SVC and RA.

X-ray is less reliable than conductance (subjective vs objective) and is vulnerable to intraobserver variability related to interpretation of a two-dimensional projection of three-dimensional soft tissue organs.[10] In fact, among radiologists, discrepancies in interpreted catheter tip position on anterior-posterior chest X-rays has been shown to occur in 41% of the cases.[26] In addition, conductance is more direct than other nonfluoroscopic PICC navigation and tip location technologies such as electrocardiographic, Doppler flow, and stylet-aided magnetic guidance.[14-20] Electrocardiographic and Doppler flow methods have been controversial and not widely adopted in the clinic, while stylet-aided magnetic guidance provides a non-anatomically based relative assessment of PICC position. These and other bedside guidance technologies (eg, Swan-Ganz catheters[27]) exist and rely on physiological measurements to confirm catheter location. The physiologically based PICC technologies have inherent limitations since they are used as a surrogate for direct anatomical measurements. The conductance-based method (ie, the CGW

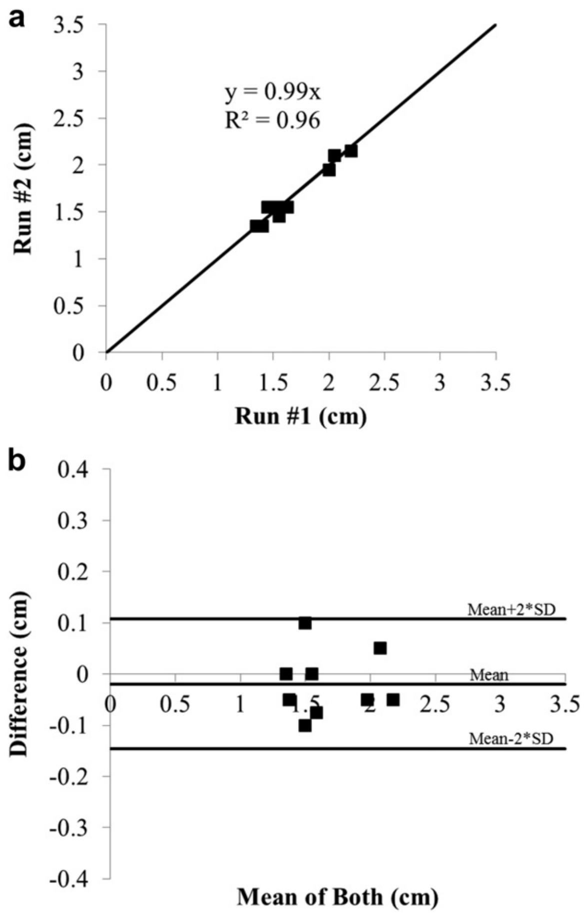


Fig 5. Repeatability data for bench experiments showing **(a)** the repeat runs for the peripherally inserted central catheter (PICC) placement and the **(b)** Bland-Altman analysis. In **(a)**, the *solid dark line* is the identity line and the *smaller dark line* is the regression (not seen, but overlaid on the identity line). *SD,* Standard deviation.

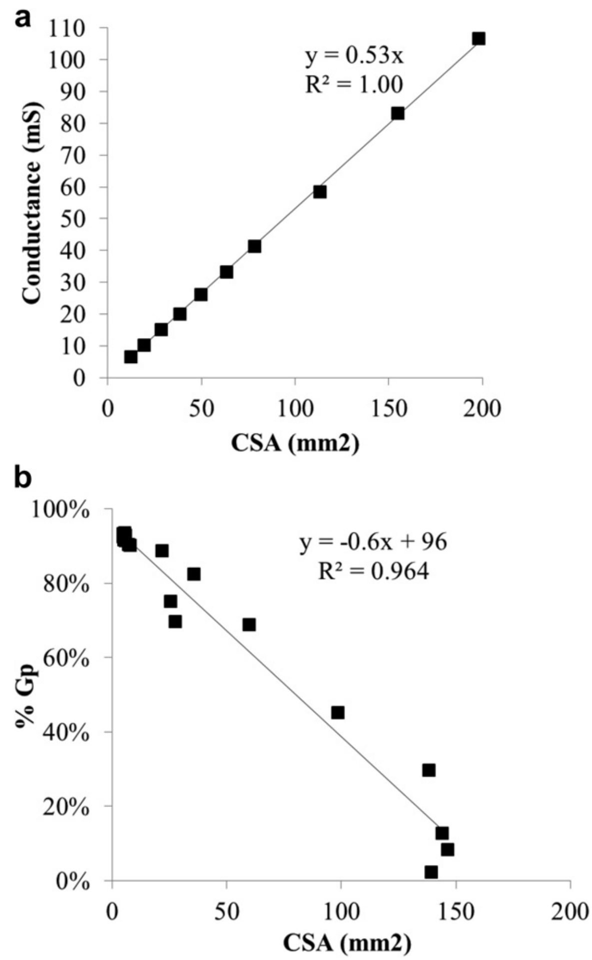
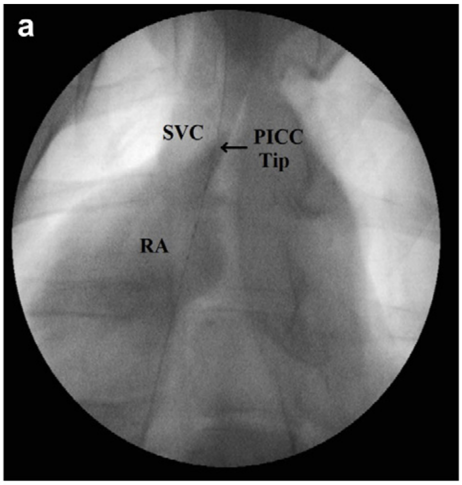


Fig 6. The linear relationship between **(a)** the total conductance (G_T) and cross-sectional area (*CSA*) on the bench and **(b)** the percentage of G_T that is directly related to parallel conductance (*Gp*) as a function of CSA from in vivo data.

system) is an unbiased physical measurement directly related to vascular CSA with high accuracy and repeatability for anatomical identification (Figs 2-7; Table). The clinician can easily place the PICC in the SVC, the cavoatrial junction, or the RA, depending on clinical guidelines, and can thus study various outcomes based on PICC location.[7-10]

The use of the CGW system for PICC line placement has high clinical significance. Multiple benefits are gained through use of the CGW system, which include: (1) an anatomically based guidance system, (2) accurate and repeatable guidance, (3) ease of use, (4) virtually no increase in time for placement (ie, combined with workhorse guidance), (5) potential for reduced cost (ie, better accuracy can lead to potentially fewer follow-up X-rays for readjustment), (6) potential to reduce X-ray exposure, and (7) possibly less time from the initial PICC placement to actual therapy delivery to the patient.

Guidance using the CGW system flows easily within standard clinical procedures, and system usage requires only limited training. Guidewires are already used by radiologists in PICC placement procedures, and the current technology integrates within this platform. Unlike other guidance tools, the CGW system does not require attachment to other vitals (ie, electrocardiogram) and can be used with any type of PICC from multiple catheter manufacturers. Accurate placement using the CGW system may eliminate the need for X-ray confirmation, thus saving time and reducing procedural costs. Further cost savings can be made by including the guidewire in a standard PICC line kit (ie, the CGW also functions as a standard guidewire). The technology is not limited just to PICC applications, but can also be expanded for any central catheter placement (ie, Quinton catheter, Hickman catheter, etc). Subsequent system iterations will allow for full-system automation (ie, no required user interpretation) with battery powering for portable usage in the clinic or offsite location using a small console/hand-held device (eg, a smartphone).



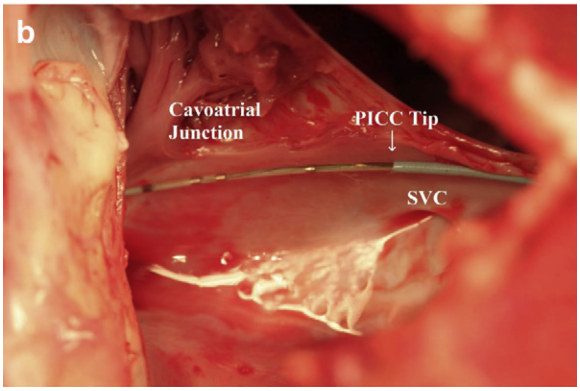


Fig 7. Confirmation of conductance guidewire (CGW) navigation of peripherally inserted central catheter (*PICC*) tip delivery to the distal superior vena cava (*SVC*) using **(a)** fluoroscopy and **(b)** postmortem direct visualization. The *arrows* point to the PICC line tip in the distal SVC. Fluoroscopy was not used to aid in the guidance but is shown here as a confirmation. The PICC was offset 2 cm from the middle electrodes and fixed in place during advancement. The X-ray and postmortem image both show that the middle CGW electrodes have accurately located the cavoatrial junction, and the PICC tip is therefore offset 2 cm distal from this location in the distal SVC. In **(b)**, the distal electrode is in the right atrium (*RA*), the middle measurement electrodes are in the cavoatrial junction (see the trabeculations just above the middle electrodes), and the proximal electrode is in the SVC.

The study was completed in swine venous vasculature of similar size and structure to normal humans, but not in diseased vessels with venous congestion, thrombosis, or subclavian vein or SVC stenosis. While the accuracy of the system is not expected to diminish in these circumstances, future animal and human studies should examine the utility of the CGW technology under these diseased conditions. For the navigation portion of the system, the knowledge of a continuous and sustained drop in conductance is required before the system/user knows that advancement is occurring in an incorrect direction. Therefore, passage through a stenotic or thrombolytic region would not provide the same sustained conductance drop feedback as would be seen if advancement was occurring in the incorrect direction. Implants in the venous system, like vena cava filters or pacemaker leads, may also affect CGW navigation. However, placement of PICCs is generally counterindicated for patients with SVC filters, and preliminary experiments have shown that coated devices (eg, pacemaker lead bodies) do not negatively impact CGW navigation due to the insulative barrier coating. No arrhythmias were seen during simultaneous CGW and pacemaker use. Inherent electrical heart activity (ie, SA node) does not interfere with the CGW because a local current is injected by the device, and the measured voltage drop has a much greater relative amplitude and frequency compared with the surrounding tissues. Surprisingly, in this study, the in vivo accuracy was slightly more accurate than the bench studies. This may be due to the 2.5-mm resolution for the in vivo studies, as compared with the 1-mm resolution for the bench experiments (ie, not statistically different).

Table. Postmortem PICC tip location for each animal. The target location for the PICC tip was 2 cm from the cavoatrial junction for all animals

Animal	*Weight, kg*	*Measured position proximal to cavoatrial junction, cm*	*Difference from desired target, cm*
1	63	1.75	0.25
2	68	2	0
3	47	2	0
4	48	2	0
5	46	2	0
6	48	2	0

PICC, Peripherally inserted central catheter.

All the experiments were performed using a 0.035" diameter CGW. Some PICCs are 0.035" compatible, but most are 0.018" compatible or smaller. Future development and validation is needed to develop a 0.018" CGW. No anticipated difference is expected in the future outcomes with a <0.035" CGW, since conductance measurements are not affected by guidewire size. When placed by a clinician, PICCs can be advanced over the wire, but they are typically placed only using a stylet or with no guidewire when placed by a nurse. Therefore, future work will also be completed to develop a hybrid guidewire-stylet version of the CGW (short stylet with a floppy atraumatic tip) to be used for concurrent advancement of the CGW and PICC by nurses.

In conclusion, the CGW system provides an anatomically based, accurate, safe, and unbiased method for nonfluoroscopic PICC delivery that fits within the current clinical procedural workflow. Future efforts will be made to automate the detection of the desired PICC line location, make the device user-friendly for nurses, and prove the utility of the device in man.

AUTHOR CONTRIBUTIONS

Conception and design: MS, DB, BJ, ST, BC, GK
Analysis and interpretation: MS, ST, BC
Data collection: MS, DB, BJ
Writing the article: MS, DB, GK
Critical revision of the article: MS, DB, ST, GS, GK
Final approval of the article: MS, DB, BJ, ST, BC, GS, GK
Statistical analysis: MS, GK
Obtained funding: GK
Overall responsibility: GK

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APPENDIX (online only).

The conductance guidewire contains four distal electrodes with the outer two injecting a constant mean AC current (I) and the inner two measuring a voltage drop (V) and in turn the total conductance ($G_T = I/V$). When placed inside a blood vessel, Ohm's Law (Eq. 1) states that the total measured conductance (G_T) is related to the cross-sectional area (CSA) of the blood vessel, the blood conductivity (σ), the spacing between the measurement electrodes (L), and any parallel conductance loss (Gp) as follows:

$$GT = I/V = CSA * \sigma/L + Gp \qquad \text{(Eq. 1)}$$

The value for G_T is known (measured and displays across the middle electrodes), σ is constant for blood (hematocrit and temperature will not change during the procedure), L is a known constant (the spacing between the middle electrodes, 2 mm), and Gp is inversely proportional to CSA (Fig 6, *b* and reference[24]). Therefore, since the variables are either measured, known, or inversely related to CSA, relative changes in CSA during guidewire advancement are observed simply by monitoring changes in G_T (Eq. 2); namely:

$$GT \propto CSA \qquad \text{(Eq. 2)}$$